German Utility Model U1 Register No. G 9,102,312.2

Translated from German by the Ralph McElroy Co., Custom Division
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Code: 1706-39808

FEDERAL REPUBLIC OF GERMANY
GERMAN PATENT OFFICE
UTILITY MODEL U1

Register No.:	G 9,102,312.2
Int. Cl.:	A 61 M 36/04
Filing Date:	February 27, 1991
Registration Date:	June 25, 1992
International Publication Date:	August 6, 1992

DEVICE FOR THE TREATMENT OF STENOSES OR GROWTHS

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The present invention relates to a device for the treatment of stenoses or growths in vessels which transport body fluids, with a treatment catheter which can be inserted into the vessel according to the generic concept of Claim 1.

Such a device for the treatment of stenosis is known, for example, from the paper "Laser Balloon Angioplasty: An Optical and Thermal Analysis," by A. J. Welch and Wai-Fung Cheong from

the Biomedical Engineering Program, The University of Texas at Austin, Austin, Texas, 78712, pages 68 to 95. In that paper stenoses are treated with laser beams. For this purpose a light conducting [optical] fiber is placed in a balloon catheter, whose tip has a form such that light is scattered. The pressurized medium used to inflate the balloon must be selected in such a manner that it does not absorb the laser beams.

Furthermore DE-OS 3,028,089 describes a device for the dilation of a blood vessel occlusion using a treatment catheter at whose tip a balloon is attached whose circumference can undergo a definite expansion. This balloon is placed in the area of the narrowing and filled through a catheter with fluid so that the tissue which causes the narrowing is pressed into the wall of the blood vessel and remains there. Using this method it is frequently not possible to avoid the development of tears, during the dilation, in the intima which is the innermost wall of the vessel system. As a result there is the risk that the internal vessel layers are in part separated and occupy the free inner space of the blood vessel, which could result in the vascular system in occlusions and/or decreases in restricted blood flow through organs which are supplied by the blood vessel concerned. Thus, for example, an infarction can develop in coronary vessels as a result of insufficient blood supply.

In all these known methods and procedures, particularly in percutaneous transluminal coronary angioplasty, the treated stenoses frequently become stenosed again. This is presumably the result of a proliferation of smooth muscle cells which are apparently induced and maintained by the growth factors released from the thrombocytes as a result of a mechanical alteration of

the balloon unfolding in the intima. The treatment with laser light or an expansion using a higher temperature by direct heating of the treated section with appropriate means in this view hardly presents an improvement.

The present invention therefore relates to the task of describing an installation for the treatment of stenoses or growths in vessels which transport body fluid, by means of which it is possible, after a dilation, to prevent a subsequent proliferation or to completely prevent proliferations or at least [prevent] to a large extent.

This task is solved by the characteristics indicated in the characterizing part of Claim 1.

The invention is characterized in particular by the fact that, using a radiation source which is located in or at the catheter, and which can be inserted or introduced, an irradiation can be conducted, during the dilation or after it, particularly with weak radioactive radiation, using in particular a radiation source which emits α- or β-radiation. As a result of this irradiation, the efficacy of the growth factors released during the dilation is decreased considerably or eliminated completely. This guarantees that, after the radioactive irradiation of a dilated section, no new stenosis develops or at most such a new stenosis develops only to an extent which no longer endangers the condition of the patient. This treatment, in particular with weak radioactive radiation, also prevents a disadvantageous effect on healthy irradiated vessel parts or vessel sections. The irradiation is possible with the device according to the invention in a simple manner and at precisely defined positions in the vessel lumen. Because the pathway traveled by the

radiation is very short before the places to be treated are reached, only a low radiation dose is required for the treatment. This in turn guarantees that tissue and vessel areas in the vicinity of the treated place are not exposed to the dangerous dose of radiation.

Other advantageous details of the invention are indicated in the secondary claims and they are described in further detail with reference to the embodiment examples of appropriate treatment catheters illustrated in the drawing.

In the drawings:

Figure 1 and 2 each show a cross section of a blood vessel with a stenosis into which a treatment catheter has been introduced by means of which a balloon dilation and an irradiation can be conducted,

Figures 1a and 2a each show a cross section of the treatment catheter along line I-I of Figure 1, or along line II-II of Figure 2,

Figure 3 shows the double balloon catheter in the blood vessel in a lateral cross section, and

Figure 3a shows a cross section of the same along the line III-III of Figure 3.

In Figure 1 the reference number 1 is used to designate a treatment catheter, which is surrounded with an expandable balloon 4 in section 2 of the closed end 3. Within the area 2, the wall 5 of the treatment catheter 1 is provided with an opening 6, through which a gaseous or liquid medium, for example a salt solution, can be introduced under pressure into the balloon 4.

The treatment catheter 1 is inserted in a vessel 7, for example in an artery or vein, and it is brought with balloon 4 into an area 8 of the vessel 7, in which there is a stenosis 9 or a growth. As a result of the pressure of the gaseous or liquid medium, the balloon 4 is expanded and thus the stenosis 9 or growth is dilated.

During and/or after the dilation, the treated area 8 of the vessel 7 can be irradiated from outside with a weak X-ray or radioactive irradiation, as indicated by the arrows 10.

The irradiation can take place in one or in several time intervals, during which a relatively small radiation dose of approximately 5-8 Gy (gray) is applied for an irradiation duration which in each case is selected so as to correspond in a standard manner to the position and the consistency of the stenosis or growth to be treated, over an area of 5 cm^2, for example.

To mark the position, where an irradiation is to be performed from outside, it is possible to apply an external marking 13 before, during or after the dilation onto the external surface 11 of the tissue 12 which is adjacent to the vessel 7. This external marking is advantageously arranged in such a manner that the direction of emission of the irradiation 10 from the outside occurs vertically or approximately vertically onto area 8 of the vessel 7.

However, it is more advantageous to conduct the irradiation using weak X-ray or radioactive radiation, for example, α- and/or ß-particles, if the irradiation is conducted from the vessel lumen. This can be achieved by inserting a radioactive radiation

source 16, which is attached to a guide wire 15, into the lumen of the treatment catheter 1, optionally after the removal of a guide mandrel 14, which may be necessary for the introduction of the treatment catheter and which is represented in Figures 1 and 1a by broken lines, where the radiation is emitted by the radiation source which is inserted into the area 8 of the vessel 7. As material for the radiation source 16, for example, it is possible to use iridium-192, whose half-life is 70 days. This results in a local irradiation of the area 8, which can take place during and/or after the dilation by expansion of the balloon 4 with a lower radiation dose than in the case where the irradiation takes place from outside. For example, three irradiations, each with 5 Gy, or two irradiations, each with 5 Gy, or two irradiations each with 6 Gy, can be sufficient to achieve the desired success if they are used in each case at the treatment durations which are standard for such irradiations, depending on the position and the consistency of the area to be treated or the stenosis or growth to be treated.

As indicated by broken lines in Figures 1 and 1a, the treatment catheter 1 can also have an intermediate wall 18. This results in a subdivision of the lumen of the treatment catheter 1 into two ducts 19 and 20. The top duct 19, whose wall 5 has the orifice 6, is used for the supply of the pressurized medium used to inflate the balloon 4. In the lower duct 20 the radiation source 16 can be inserted by means of the guide wire 15, and this can occur before, during or after the dilation of the stenosis 9. There is also the possibility of placing the radiation source 16 solidly at or in the treatment catheter 1 within the lumen in section 2 of balloon 4. This occurs preferably in the lumen or

in a duct or as a result of a shaping of the wall 6 of the treatment catheter 1 or as a result of the arrangement of the radiation source 16 outside on wall 6, particularly in a recess. It is essential here that the radiation source 16 is arranged in the area of section 2, preferably in its middle, so that it is advantageously in the middle, or at least approximately in the middle with respect to area 8.

In the case of a radiation source 16 which can be moved, for example, by means of guide wire 15, the position of the radiation source 16 can be established at any time with precision, and its position can be observed, for example, on a screen.

In order to achieve a better centering of the radiation source 16 within the lumen of the treatment catheter 1, the latter can be equipped according to Figure 2 and Figure 2a with a central or approximately central supply duct 21. This duct may be in a fixed position in the lumen 24, for example, by means of longitudinal intermediate walls 22 and 23. At the same time ducts 19 and 20 are formed, where the lower duct 20, for example, can have an opening 30, which is present outside of the section 2 of the balloon 4 and which opens into the vessel lumen 24. The tip 25 of the treatment catheter 1 has an opening 26, which forms the opening of the supply duct 21. The radiation source 16 is inserted or can be inserted in the latter. The radiation source 16 here consists, for example, of an iridium pin having a length of approximately 2-3 cm and a diameter of 0.3-0.6 mm, particularly 0.4 mm, and which is attached at the guide wire 15. The treatment catheter 1 with the supply duct 21 can also be closed at tip 25, so that in that case duct 21 is closed.

According to Figures 3 and 3a the treatment catheter 1 can be equipped with two balloons 4.1 and 4.2, arranged at an interval 27 with respect to each other. If more than two ducts are used, it is possible, for example, to inflate the two balloons 4.1 and 4.2 independently.

Such a double balloon catheter is known from European Patent No. 0,080,436 or U.S. Patent No. 4,573,966.

In the embodiment example, there is again a supply duct 21, and in addition intermediate walls 22, 23 as well as additional intermediate walls 28, 29. Four ducts 31 to 34 are formed by these intermediate walls 22, 23 and 28, 29, where the upper duct 31 has an opening 35, which opens into the treatment section 36 between the two balloons 4.1 and 4.2, in which section the stenosis 9 to be treated is located, which in this case is removed by a fluid which dissolves this tissue. The bottom duct 33 can have an opening 37, which also opens into the treatment section 36. It is possible thereby to rinse the treatment section 36 through ducts 31 and 33. The radiation source 16 is located in the lower duct 33 in the embodiment examples illustrated.

An opening 38 is located in duct 34 within the balloon 4.1, so that the balloon 4.1 can be inflated by a pressurized medium, from outside. Accordingly, there is an opening, not visible in the drawing, in duct 32 in the area of the balloon 4.2, by means of which the latter can be inflated. In this catheter type as well, the radiation source 16 can be located in the central duct, for example, in the supply duct 21. In this case, as in the arrangement according to Figures 2 and 2a, the radiation source 16 can be pushed beyond the tip 25 of the treatment catheter 1

out of the supply duct 21, and the treatment catheter 1 can be removed from the area of the stenosis 9 or completely out of the vessel 7, and the radiation source 16 can be placed freely in lumen 24 of the vessel 7 with observation on a screen in area 2 or 36 of the stenosis 9. It is also possible to remove the treatment catheter 1 completely from the vessel 7 and to place the radiation source 16 subsequently with a guide wire 15 with observation on a screen and optionally after prior placement of an external marking 14 (Figure 1). After a corresponding irradiation time, the radiation source 16 is removed from the vessel 17.

According to an additional embodiment of the present invention, it is also possible to use as radiation source 16 a radiation emitting fluid which is introduced into the lumen 24 or into one of the ducts 19, 20, 21, 31 to 34. In the case of the use of a radiation emitting fluid as well, the radiation dose can be kept relatively low, again, for example, in the range of 5-8 Gy.

Even if the main area of application of the device according to the invention is reduction or complete elimination of stenoses in vessels which transport body fluids, the device is also suited for the reduction or the elimination of growths, particularly after vascular operations. It is preferred to use the device according to the invention for the treatment of growth which develop as a result of the suturing of veins or arteries, particularly in bypass operations.

Claims

1. Device for the treatment of stenoses or growth in vessels which transport a body fluid by means of a treatment catheter which can be inserted into the vessel and which has at least one balloon which can be inflated with pressure via a lumen or a separate duct from outside, characterized by the fact that in the treatment catheter (1) a radioactive radiation source (16) is arranged rigidly or in a movable manner, or such a radiation source (16) can be inserted into the lumen (24) or into a duct (19, 20, 21; 31 to 34) of the treatment catheter (1).

2. Device according to Claim 1, characterized by the fact that a treatment catheter (1) has a balloon (4) which is arranged in a section (2) of its end (3), and by the fact that the radiation source (16) is arranged within the section (2).

3. Device according to Claim 2, characterized by the fact that the radiation source (16) is located in the middle or at least approximately in the middle of this section (2).

4. Device according to Claim 1, characterized by the fact that the treatment catheter (1) has two balloons (4.1, 4.2) located at a distance (27) in a treatment section (36), and by the fact that the radiation source (16) is arranged in the area of the same interval (27).

5. Device according to Claim 4, characterized by the fact that the radiation source (16) is arranged in the middle or approximately in the middle in the area of the interval (27) of the two balloons (4.1, 4.2).

6. Device according to one of Claims 1 to 5, characterized by the fact that the radiation source (16) is arranged in a duct

(19, 20, 21, 31 to 34) centrally in the lumen (24) of the treatment catheter (1).

7. Device according to Claim 6, characterized by the fact that one of the ducts is a supply duct (21) which opens in an opening (26) at the tip (25) of the treatment catheter (1).

8. Device according to one of Claims 1 to 7, characterized by the fact that a treatment catheter (1) is provided with a guide mandrel (14) and by the fact that the radiation source (16) can be inserted after the removal of the guide mandrel (14) into its duct or lumen (19, 20, 21, 31 to 34).

9. Device according to one of Claims 1 to 8, characterized by the fact that the radiation source (16) is provided in the supply duct (21) or it can be inserted in it and extracted through the opening (26) of the supply duct (21) at the tip (25) of the treatment catheter (1), out of the latter.

10. Device according to one of Claims 1 to 9, characterized by the fact that the balloon (4) or the two balloons (4.1, 4.2) are connected via an opening (6 or 35) provided in one of their sections (2) with a duct (19 or 32, 34) which can contain a pressurized medium, and by the fact that this duct (19) or these ducts (32, 34) are separated from the duct (21, 20, 33) in which the radiation source (16) is located or in which it can be inserted.

11. Device according to one of Claims 1 to 10, characterized by the fact that the radiation source (16) is a weak radioactive radiation.

12. Device according to one of Claims 1 to 11, characterized by the fact that the radiation source (16) consists of iridium-192.

13. Device according to Claim 12, characterized by the fact that the radiation source (16) consists of an iridium segment with a length of approximately 2-3 cm and a diameter of approximately 0.3-0.6 mm, particularly approximately 0.4 mm.

14. Device according to one of Claims 4 to 13, characterized by the fact that several ducts (31, 32, 33, 34) are provided and at least one of these ducts (31 and/or 33) has, in the area (27), an opening (35 or 37) which opens between the two balloons (4.1, 4.2) into the treatment section (36).

15. Device according to one of Claims 1 to 14, characterized by the fact that a radiation emitting fluid is provided, which is introduced as radiation source into the lumen (24) or into one of the ducts (19, 20, 21, 31 to 34).

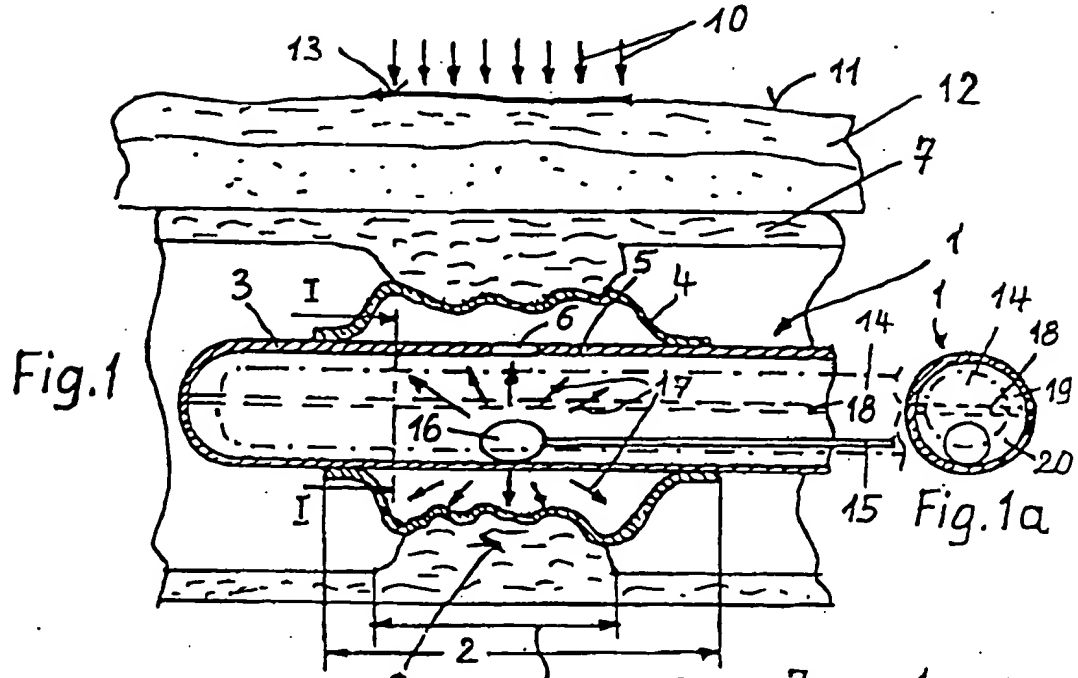

Fig.1

Fig.1a

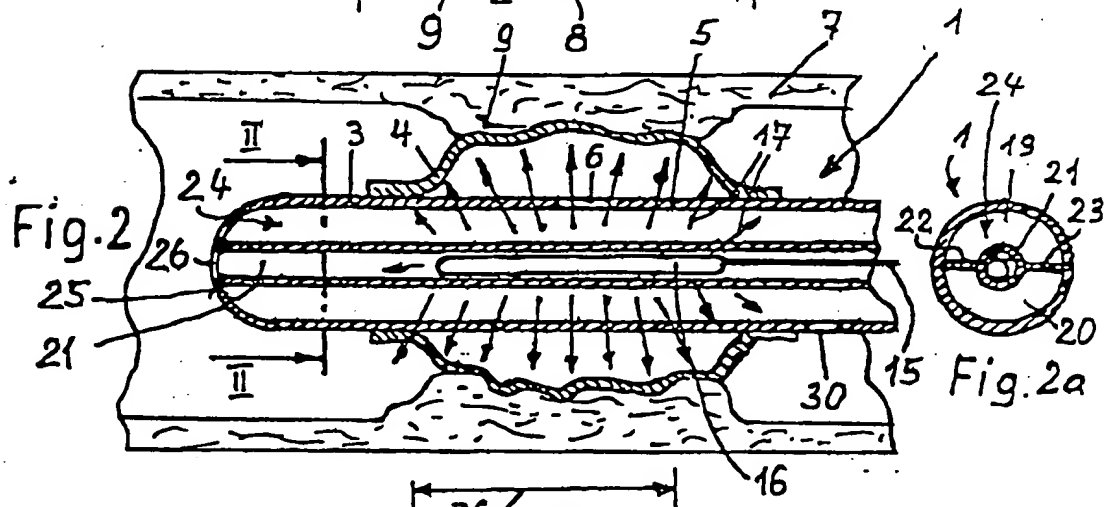

Fig.2

Fig.2a

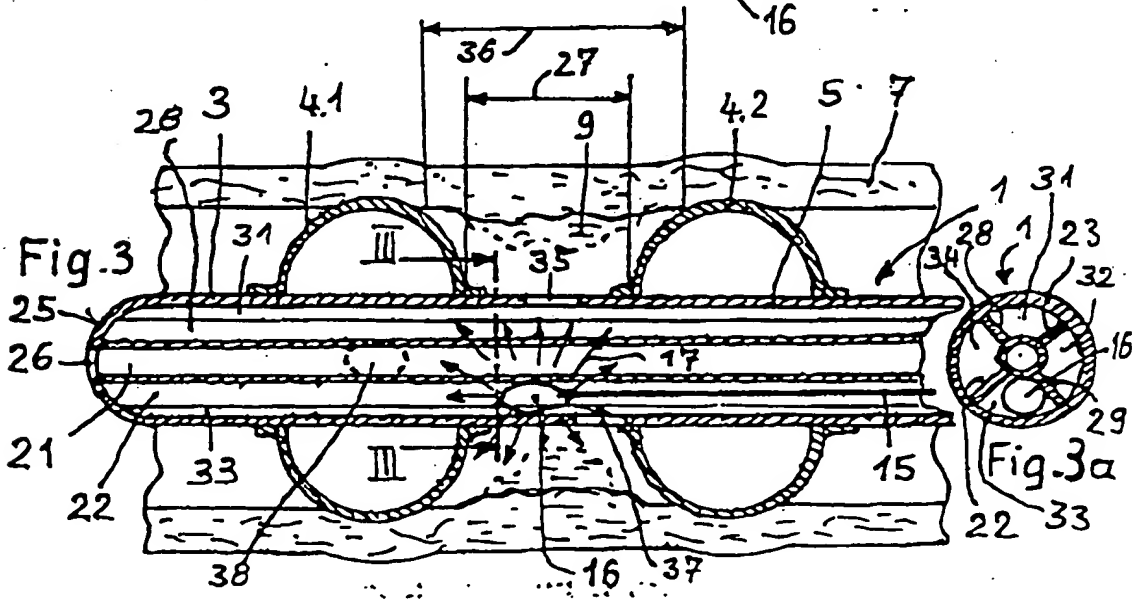

Fig.3

Fig.3a